SEP 5 2012

Section 5 **510(k) SUMMARY** **Traditional 510K**

Submitter Information:

Submitter:	MEDCOMP® 1499 Delp Drive Harleysville, PA 19438 (215) 256-4201 Telephone (215) 256-9191 Fax
Contact:	Rosanna Severini, Compliance Director
Date Prepared:	August 10, 2012

Device Name:	"X" Series PD Catheter
Common Name:	Peritoneal Dialysis Catheter
Classification Name:	Peritoneal Dialysis Catheter & Accessories
C.F.R. Section:	876.5630
Classification Panel:	Gastroenterology and Urology
Class:	II, 78 FJS

Predicate Devices:

Primary: K071167, Flex-Neck® ExxTended™ PD Catheter & Accessories, concurrence date August 31, 2007. Class II CFR §876.5630
K950042, Swan Neck Presternal Peritoneal Dialysis Catheter, concurrence date December 15, 1995. Class II CFR §876.5630
K915490, Peritoneal Dialysis Catheter, concurrence date February 2, 1994. Class II CFR §876.5630

Secondary: K113487: Hemo-Cath
K110424: CT Power Injectable implantable Infusion Port

Device Description:

The "X" Series PD Catheter is comprised of a silicone rubber, coiled tip, single polyester cuff abdominal catheter segment that is joined with a titanium double bared connector to a silicone rubber, double polyester cuff subcutaneous extension catheter possessing a preformed tubing arc bend between the two cuffs. The abdominal catheter segment is implanted into the peritoneal cavity. The attached subcutaneous extension piece allows remote location of the catheter skin exit site away from the lower abdominal region.

The catheter will be sold in two kit configurations, as the catheter only with a female luer, clamp, and male luer end cap and titanium connector. The catheter set will also include the addition of a dilator/sheath introducer, guidewire, scalpel, introducer needle, tunneling tool, gauze pads and syringe.

Intended Used:

The "X" Series PD Catheter is indicated for peritoneal dialysis in adults. It is intended for use in patients who are poor candidates for conventional peritoneal dialysis catheters and are candidates for presternal insertion.

Indications for Use:

The "X" Series Catheter is indicated for chronic peritoneal dialysis.

The extended length of the "X" Series Catheter makes it especially applicable for peritoneal dialysis patients when it is necessary to locate the skin exit site remote from the usual lower abdominal region. The catheter may be particularly indicated in patients with obesity, floppy abdominal skin folds, urinary or fecal incontinence, chronic yeast intertrigo, intestinal stomas, or in patients who desire to take deep tub baths.

Comparison to Predicate Devices:

The "X" PD Series Catheter is substantially equivalent to the predicate devices in terms of intended use, materials, anatomical location, basic design, performance, labeling, manufacturing process and method of sterilization.

Performance Standards:

Performance standards have not been established by the FDA under section 514 of the Federal Food, Drug and Cosmetic Act.

Performance Testing:

Air Leakage
Liquid Leakage
Gravity Flow
Force at Break
Pull Force Testing
Priming Volume
Effects of Site Care Agents
Cuff Shear Testing
Tip Separation Force

Biocompatibility:

Results for all biocompatibility testing demonstrate the materials used meet the requirements of ISO 10993. All materials have been cleared under past approved 510K's.

Technological Characteristics:

The principles of operation are the same as the predicate devices. There are no new questions raised regarding the safety or effectiveness of the device.

Summary of Substantial Equivalence:

The proposed device meets the performance criteria of design verification as specified by ISO standards, guidance documents and test protocols. The proposed device has the same intended use, operation and function as the predicates. There are no differences that raise new issues of safety and effectiveness. The proposed device is substantially equivalent to the legally marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

SEP -5 2012

Ms. Rosanna Severini
Compliance Director
Medcomp (Medical Components)
1499 Delp Drive
HARLEYSVILLE PA 19438

Re: K121383
Trade/Device Name: "X" Series PD Catheter
Regulation Number: 21 CFR§ 876.5630
Regulation Name: Peritoneal dialysis system and accessories
Regulatory Class: II
Product Code: FJS
Dated: August 24, 2012
Received: August 24, 2012

Dear Ms. Severini:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. However, you are responsible to determine that the medical devices you use as components in the kit have either been determined as substantially equivalent under the premarket notification process (Section 510(k) of the act), or were legally on the market prior to May 28, 1976, the enactment date of the Medical Device Amendments. *Please note:* If you purchase your device components in bulk (i.e., unfinished) and further process (e.g., sterilize) you must submit a new 510(k) before including these components in your kit. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, and labeling, and prohibitions against misbranding and adulteration.

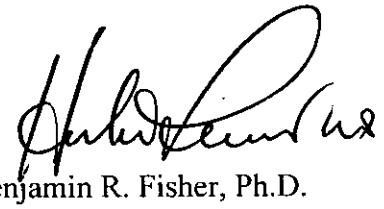
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Indications for Use

510(k) Number (if known): K121383

Device Name: ___ "X" Series PD Catheter _____

Indications for Use:

The "X" Series Catheter is indicated for chronic peritoneal dialysis.

The extended length of the "X" Series Catheter makes it especially applicable for peritoneal dialysis patients when it is necessary to locate the skin exit site remote from the usual lower abdominal region. The catheter may be particularly indicated in patients with obesity, floppy abdominal skin folds, urinary or fecal incontinence, chronic yeast intertrigo, intestinal stomas, or in patients who desire to take deep tub baths.

Prescription Use ___X____ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K121383